

Division of Communicable Disease Control (DCDC)



Appendix A: ELR Requirements

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Introduction

Purpose of this document

The purpose of this document is:

- To provide a vehicle for presenting ELR business requirements for consideration and review.
- To provide supporting information about the procurement of a web-based electronic disease surveillance system for the California Department of Health Services (CDHS), Division for Communicable Disease Control (DCDC) and it's affiliated Local Health Departments (LHDs).

This document contains the following information:

- **Scope:** a brief high-level scope of the project.
- **Business requirements:** technical and business requirements for State and Local Health Departments (LHDs) for electronic laboratory reporting.

Note: For information about the ELR companion project **Web-CMR** please see the companion Web-CMR RFP (07-65623).

Scope of Web-CMR & ELR Project

This section describes the proposed scope of the ELR Project.

The ELR system is expected to be a component or module of a full disease reporting system (i.e., Web-CMR and ELR together), not a standalone ELR system. Once ELR data/records are captured, as described in these ELR requirements, the data must be routed/shared to WebCMR via tight integration of these two disease reporting system components. ELR data will then either become a part of an existing case in Web-CMR or, if no match exists, will initiate the creation of a new case record in Web-CMR. All functions and processes in the Web-CMR requirements (*Web-CMR-Business-Requirements-V5-Final Draft.doc*) that apply to case-associated data will also apply to laboratory record data collected by ELR after such data are routed to Web-CMR.

The ELR requirements contained in this document focus on the collection, validation, configuration, tracking, security, aberration detection and other functions specific to laboratory reports/data, using applicable standards. Since these data, once collected as described, are to be routed to Web-CMR, there is no need to replicate case processing and other functions within the ELR system. The primary purpose of the ELR system is to serve as a mechanism to collect laboratory reports from laboratories, whether via batch submission or web-entry, and deliver them to Web-CMR.

Requirements

Note on ELR Technical Requirements:

As a tightly-coupled companion to the Web-CMR application, the ELR application technical requirements must meet the WebCMR comprehensive technical requirements as expressed in the Web-CMR requirements document.

1.1 ELR Business Requirements

1.1.1 ELR - Laboratory Data Input Requirements			
Rank	Demo	Req ID	Description
M	Y	1.1.1.1	The System must provide for a method of web-based entry of laboratory test reports using forms for entry of specific patient, condition (e.g. reason for test, when available) and results information. All relevant laboratory information, required to meet legal mandates (California Code of Regulations, Title 17, Section 2505) and additional information consistent with needs for local reporting, disease registry data and other uses, must be collected and enforced through form validation and effective context sensitive help.
M	Y	1.1.1.2	The System must provide the ability to receive, parse and discretely populate all elements contained in all required and conditional segments (when appropriate) within unsolicited electronic laboratory result messages that are compliant minimally with the current PHIN (HL7 v 2.5 Implementation Guide at the time of this writing) reference implementation standards as an ORU^R01 message type. The reference vocabulary for these messages is contained in the PHIN Vocabulary Access and Distribution System or PHIN VADS. In addition, the System must be fully compliant with the functional requirements and process flows detailed in PHIN's Connecting Laboratory System standards for the acceptance of results messages for laboratory testing by public health, hospital, clinic, commercial and reference laboratories. The System shall be updated to maintain compliance with published standards as they are enacted.
D	Y	1.1.1.3	<p>The System must upon receipt of laboratory result message where the expected coded vocabulary element (including LOINC and SNOMED) fails to properly validate, flag the transaction and provide a notification to the vocabulary services administrator to investigate. The flag should intuitively communicate the type or classification of error so it may be rapidly and accurately routed to one or more individuals for follow-up (e.g. DBA, System administrator, vocabulary domain expert, etc.).</p> <p>Details: Potential errors in validation are numerous and Web-CMR requirements 2.2.3.23 through 2.2.3.26 (form validation) address some of these cross cutting issues. Scenarios where validation is expected to catch errors and provide an exception report to the vocabulary administrator include meta-validation (e.g. a coded element is missing or populates the wrong segment) and syntactic validation (e.g. a coded element is of the wrong datatype, structure, data length, etc.).</p>

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			Where the System is unable to identify or classify the error, a notification should be generated immediately for resolution by the assigned help desk staff.
D	Y	1.1.1.4	<p>For users with the appropriate security permission, the System must be configurable over time to receive lab reports containing new data elements as additions, deletions or modifications to tests, drug susceptibility diagnostics, methods and other changes occur.</p> <p>The System must also be configurable over time as lab reporting regulations (e.g. changes to CCR Title 17, Section 2505), reference implementations (e.g. PHIN HL7 implementation guides) and other requirements to business or technical processes change.</p> <p>The System must provide the ability to maintain, with limited or no direct vendor involvement the lists of LOINC lab tests and diagnostic tests and SNOMED results and organisms codes. Maintenance of vocabulary data elements (and other data standards) will require continual development and refinement by CDHS domain experts. A method to house, store, retrieve, curate and annotate these vocabulary elements within a central repository is desirable. Management of this information may be supported by the vendor, but the data and structure should be readily available and usable if exported, if the vendor fails to provide support or is no longer engaged in the project.</p>
D	Y	1.1.1.5	<p>This Requirement must be included in the Proof of Concept (POC) Demonstration. The System must provide for the ability to assign the status of a laboratory report. The data elements and value domains used to exchange this information must be harmonized with the set of permissible values established by PHIN, however agreed upon extensions or mapping of synonymous terms to this value domain can be agreed upon for use between public health partners and CDHS.</p> <p>Examples include:</p> <ul style="list-style-type: none"> • Final • Preliminary • Pending • Corrected
M	Y	1.1.1.6	<p>This Requirement must be included in the Proof of Concept (POC) Demonstration. The System should be able to track the following time elements related to specimen collection, submission and analysis:</p> <ul style="list-style-type: none"> • The date/time the specimen was collected.

1.1.1 ELR - Laboratory Data Input Requirements			
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			<ul style="list-style-type: none"> Date final tests (e.g. follow-up, corrected, serial) were completed and reported or their status changed. (Example, OBR-24).
D	N	1.1.1.7	<p>For new laboratory partners who will begin submitting laboratory results for notifiable conditions, the System should have a separate test environment so that validation and testing of the incoming message may be performed. This process should be repeated iteratively until the ELR team is satisfied that the messages are of acceptable quality before the submitter is allowed to send messages in a production environment.</p> <p>Details: All new laboratory partners should undergo a formal test and evaluation process before "certified" to submit electronic reports in lieu of traditional methods. Once it is determined that message requirements have been met and errors have been corrected, the submitter will begin submitting reports in parallel to the routine method of report submission (e.g. by fax, telephone, postal mail and other means). The ELR solution vendor and CDHS program staff will work together to validate the performance and harmonization of both electronic and manual reporting. The culmination of this process, against a well defined set of requirements, will be a certification step that ensures that the electronic system is at least as timely and accurate and meets or exceeds the threshold number of results reported manually. Gaps between electronic submission and manual submission should be documented as well and the vendor is expected to assist with this process. Cessation of manual reporting with replacement of electronic reporting should never occur until a well described process (pending) is in place and there is no uncertainty as to the accuracy, validity and security of results submitted via ELR.</p>
D	N	1.1.1.8	<p>The System should ensure that the ELR application can audit laboratory messages via logs at every distinct system interface or application node from its entry into the State IT environment and its final destination.</p> <p>Details: After a laboratory undergoes the requisite steps to send a valid message, representative data is sent through the test environment and data that leaves the LIS and data that arrives at the ELR System are compared. Any discrepancies in data delivery should be analyzed using the logs at the various interfaces under CDHS control so that data loss due to network packet loss, interface, configuration or mapping errors or application bugs can be identified and resolved.</p>
D	N	1.1.1.9	<p>The System should ensure that all ELR messages are delivered securely, using the ebXML transport protocol and XML encryption, as specified by PHIN ebXML message transport standards. Integration of the CDC's PHIN Messaging System is required (or acceptable)?</p>
D	Y	1.1.1.10	<p>The System must have the ability to exchange HL7 messages between sending and receiving parties using positive (ACK or Acknowledgment) or negative (NACK or Negative Acknowledgment) acknowledgment protocols to verify message delivery and a mechanism to schedule repeat attempts to resend messages if there are system or network failures.</p>

1.1.1 ELR - Laboratory Data Input Requirements			
Rank	Demo	Req ID	Description
O	N	1.1.1.11	The System should have a method to identify drop-offs in lab reports from a particular reporting entity based on either a baseline average of prior submissions or if there is an agreement to send a periodic ping, whether a laboratory report is to be delivered or not, to ensure that communication between parties is maintained. Detection of a significant drop off in lab reports, or a ping or lack of a ping resulting in a negative acknowledgment would then trigger a notification to follow-up and identify if there are communication issues.